

201-16698B

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I U C L I D

Data Set

Existing Chemical : ID: 15890-25-2
CAS No. : 15890-25-2
EINECS Name : tris(dipentylidithiocarbamate-S,S')antimony
EC No. : 240-028-2
Molecular Formula : C33H66N3S6Sb

Producer related part
Company : Epona Associates, LLC
Creation date : 21.01.2004

Substance related part
Company : Epona Associates, LLC
Creation date : 21.01.2004

Status :
Memo : RT Vanderbilt

Printing date : 14.02.2008
Revision date :
Date of last update : 14.02.2008

Number of pages : 22

Chapter (profile) : Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile) : Reliability: without reliability, 1, 2, 3, 4
Flags (profile) : Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE),
Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1. General Information

Id 15890-25-2
Date 14.02.2008

1.0.1 APPLICANT AND COMPANY INFORMATION

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1.0.3 IDENTITY OF RECIPIENTS

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2.1 MELTING POINT

Value : = 345 °C
Sublimation :
Method : other: estimated with Epiwin
Year : 2004
GLP : no
Test substance :

Result : Melting Pt (deg C): 345.05 (Mean or Weighted MP)
Source : Epona Associates, LLC
Test condition : MPBPWIN v1.41
Test substance : SMILES :
[Sb](SC(=S)N(CCCCC)CCCC)(SC(=S)N(CCCCC)CCCC)SC(=S)N(CC
CCC)
CCCC
CHEM : Antimony, tris(dipentylcarbamodithioato-S,S)-,
(oc-6-11)-
CAS NUM: 015890-25-2
MOL FOR: C33 H66 N3 S6 Sb1
MOL WT : 819.03

Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
22.01.2004 (1)

2.2 BOILING POINT

Value : = 784 °C at 1013 hPa
Decomposition :
Method : other: estimated using Epiwin
Year : 2004
GLP : no
Test substance :

Result : Boiling Pt (deg C): 783.55 (Adapted Stein & Brown method)
Source : Epona Associates, LLC
Test condition : MPBPWIN v1.41
Test substance : SMILES :
[Sb](SC(=S)N(CCCCC)CCCC)(SC(=S)N(CCCCC)CCCC)SC(=S)N(CC
CCC)
CCCC
CHEM : Antimony, tris(dipentylcarbamodithioato-S,S)-,
(oc-6-11)-
CAS NUM: 015890-25-2
MOL FOR: C33 H66 N3 S6 Sb1
MOL WT : 819.03

Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
22.01.2004 (1)

2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : < 0 hPa at 25 °C
Decomposition :
Method : other (calculated)
Year : 2004
GLP : no
Test substance :

Result : VP (mm Hg,25 deg C): 2.07E-019 (Modified Grain method)
Source : Epona Associates, LLC
Test condition : MPBPWIN v1.41
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
22.01.2004 (1)

2.5 PARTITION COEFFICIENT

Partition coefficient : octanol-water
Log pow : = 12.7 at 25 °C
pH value :
Method : other (calculated)
Year : 2004
GLP : no
Test substance :

Result : Log Kow (KOWWIN v1.67 estimate) = 1
Source : Epona Associates, LLC
Test condition : KOWWIN v1.67 estimate
Test substance : SMILES :
[Sb](SC(=S)N(CCCCC)CCCC)(SC(=S)N(CCCCC)CCCC)SC(=S)N(CC
CCC)
CCCC
CHEM : Antimony, tris(dipentylcarbamodithioato-S,S)-,
(oc-6-11)-
CAS NUM: 015890-25-2
MOL FOR: C33 H66 N3 S6 Sb1
MOL WT : 819.03

Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint
22.01.2004 (1)

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in : Water
Value : < .0454 mg/l at 20 °C
pH value :
concentration : at °C
Temperature effects :
Examine different pol. :
pKa : at 25 °C
Description :
Stable : yes
Deg. product : no
Method : OECD Guide-line 105
Year : 2006
GLP : yes

2. Physico-Chemical Data

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Test substance : as prescribed by 1.1 - 1.4

Method : The determination was carried out using the Flask Method.

Remark : The column elution method was not used as the substance is a paste.

Reliability : (2) valid with restrictions

Flag : Critical study for SIDS endpoint

06.10.2006

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2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

DIRECT PHOTOLYSIS

Half-life t_{1/2} : = 26 minute(s)

Degradation : % after

Quantum yield :

INDIRECT PHOTOLYSIS

Sensitizer :

Conc. of sensitizer :

Rate constant : ca. .000000000286 cm³/(molecule*sec)

Degradation : % after

Deg. product :

Method : other (calculated)

Year : 2004

GLP : no

Test substance :

Result : Hydroxyl Radicals Reaction:
OVERALL OH Rate Constant = 286.9573 E-12
cm³/molecule-sec
Half-Life = 0.037 Days (12-hr day; 1.5E6 OH/cm³)
Half-Life = 26.837 Min
Ozone Reaction:
No Ozone Reaction Estimation

Source : Epona Associates, LLC

Test condition : Atmospheric Oxidation (25 deg C) [AopWin v1.91]

Test substance : SMILES :
[Sb](SC(=S)N(CCCCC)CCCC)(SC(=S)N(CCCCC)CCCC)SC(=S)N(CCCC)
CCC)
CCCC
CHEM : Antimony, tris(dipentylcarbamodithioato-S,S)-,
(oc-6-11)-
CAS NUM: 015890-25-2
MOL FOR: C33 H66 N3 S6 Sb1
MOL WT : 819.03

Reliability : (2) valid with restrictions

29.01.2004

(1)

3.1.2 STABILITY IN WATER

Type : abiotic

t_{1/2} pH4 : at °Ct_{1/2} pH7 : at °Ct_{1/2} pH9 : at °C

Deg. product : no

Method : other: technical discussion

Year : 2006

GLP : no

Test substance : as prescribed by 1.1 - 1.4

Remark : The test substance contains no hydrolysable groups. A hydrolysis test is
not warranted.

Reliability : (2) valid with restrictions

Technical discussion

Flag : Critical study for SIDS endpoint

14.02.2008

(5)

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

| | | |
|----------------|---|--|
| Type | : | fugacity model level III |
| Media | : | |
| Air | : | % (Fugacity Model Level I) |
| Water | : | % (Fugacity Model Level I) |
| Soil | : | % (Fugacity Model Level I) |
| Biota | : | % (Fugacity Model Level II/III) |
| Soil | : | % (Fugacity Model Level II/III) |
| Method | : | other: estimated using Epiwin |
| Year | : | 2004 |
| Result | : | Level III Fugacity Model: Mass Amount Half-Life Emissions (percent) (hr) (kg/hr) Air 0.0652 0.894 1000 Water 7.24 360 1000 Soil 28.5 360 1000 Sediment 64.2 1.44e+003 0 Persistence Time: 627 h |
| Source | : | Epona Associates, LLC |
| Test substance | : | SMILES : [Sb](SC(=S)N(CCCCC)CCCC)(SC(=S)N(CCCCC)CCCC)SC(=S)N(CCCC) CCCC CHEM : Antimony, tris(dipentylcarbamodithioato-S,S)-, (oc-6-11)- CAS NUM: 015890-25-2 MOL FOR: C33 H66 N3 S6 Sb1 MOL WT : 819.03 |
| Reliability | : | (2) valid with restrictions |
| Flag | : | Critical study for SIDS endpoint |
| 22.01.2004 | | |

(1)

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

| | | |
|---------------|---|---|
| Type | : | aerobic |
| Inoculum | : | activated sludge, domestic |
| Concentration | : | 10 mg/l related to Test substance related to |
| Contact time | : | 28 day(s) |

3. Environmental Fate and Pathways

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| | | |
|------------------------------|---|---|
| Degradation | : | 20 (±) % after 28 day(s) |
| Result | : | other: biodegradable |
| Kinetic of testsubst. | : | 0 day(s) = 0 % 10 day(s) = 18 % 20 day(s) = 22 % 28 day(s) = 20 % % |
| Control substance | : | Benzoic acid, sodium salt |
| Kinetic | : | 10 day(s) = 86 % 28 day(s) = 93 % |
| Deg. product | : | |
| Method | : | OECD Guide-line 301 B "Ready Biodegradability: Modified Sturm Test (CO2 evolution)" |
| Year | : | 2006 |
| GLP | : | yes |
| Test substance | : | as prescribed by 1.1 - 1.4 |
| Method | : | <p>The test material, at a concentration of 10 mg C/L, was exposed to activated sewage sludge micro-organisms with culture medium in sealed culture vessels in the dark at 21°C for 28 days. Following recommendations of ISO 1996 and in the published literature, the test material was adsorbed onto filter paper prior to dispersion in the test medium in order to aid dispersion of the test material in the test medium and to increase surface area of the test material exposed to the test organisms.</p> <p>The degradation of the test material was assessed by the determination of carbon dioxide produced. Control solutions with inoculum and the standard material, sodium benzoate, together with a toxicity control were used for validation purposes.</p> |
| Result | : | The test material attained 20% degradation after 28 days and therefore can not be considered to be readily biodegradable under the strict terms of conditions of OECD Guideline 301B. |
| Reliability | : | (1) valid without restriction Guideline study |
| Flag | : | Critical study for SIDS endpoint |
| 06.10.2006 | | (6) |

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Species : Daphnia magna (Crustacea)
Endpoint : reproduction rate
Exposure period : 21 day(s)
Unit : mg/l
NOEC : .02
LOEC : .063
EC50 : .084
Analytical monitoring : yes
Method : OECD Guide-line 211
Year : 2008
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : Due to the low water solubility of the test substance, solutions were made up in acetonitrile. A daily water change regimen was employed rather than continuous flow through due to instability of the test substance in the light.

Ten replicates of a single daphnid per group were exposed to the test substance at 0 (solvent control), 0.002, 0.0063, 0.02, 0.063 or 0.2 mg/L for 21 days. the numbers of live and dead adult Daphnia and live and dead young were determined daily.

Result : Results are presented as nominal concentrations.
The 14 and 21 d EC50 values for immobilization were 0.058 and 0.054 mg/l, respectively. The 21 d EC50 for reproduction was 0.084 mg/l. The 21 d LOEC was 0.063 mg/l based on the observation of significant mortalities in the adult generation. In terms of young produced per adult by day 21, no significant differences were observed. The 21 d NOEC was 0.02 mg/l based on no significant mortalities (immobilization) observed in the parental generation and no significant differences between the solvent control and 0.02 mg/l test group in terms of number of young produced per adult by day 21.

Reliability : (1) valid without restriction
Guideline study

Flag : Critical study for SIDS endpoint
14.02.2008

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4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4. Ecotoxicity

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4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION**5.1.1 ACUTE ORAL TOXICITY**

Type : LD50
Value : = 16400 mg/kg bw
Species : rat
Strain : other: albino
Sex : male/female
Number of animals : 36
Vehicle : other: cottonseed oil
Doses : 1.0, 2.1, 4.1, 8.2, 11.6, and 16.4 gm/kg
Method :
Year : 1961
GLP : no
Test substance :

Result : At the higher levels of dosage the rats showed symptoms of depression and excessive laxation, and at the highest level also became prostrated. These symptoms subsided within 24 hours. The animals appeared normal throughout the remainder of the observation period. No deaths occurred, and the post-mortem examinations disclosed no gross pathology.

Test condition : Six groups of rats (3/sex/dose) were fasted for approximately 20 hours and orally dosed with the test material in the form of 10 to 40 per cent suspensions in cottonseed oil. Animals were observed for appearance, behavior, body weight and mortality for 14 days and then sacrificed and examined grossly.

Test substance : Antimony dialkyldithiocarbamate
Reliability : (2) valid with restrictions
Flag : Critical study for SIDS endpoint

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(3)

5.1.2 ACUTE INHALATION TOXICITY**5.1.3 ACUTE DERMAL TOXICITY**

Type : LD50
Value : = 16000 mg/kg bw
Species : rabbit
Strain : other: albino
Sex : male/female
Number of animals : 12
Vehicle : water
Doses : 0.25, 1, 4, 8 and 16 gm/kg
Method :
Year : 1960
GLP : no data
Test substance :

Result : There was no mortality and all animals gain in body weight and appeared to be in good health during the observation period. Slight localized erythema was observed at the end

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of the 24-hour exposure period at all dose levels. This receded after the fourth day and the skin was normal at 7 days. Post-mortem examinations disclosed no gross pathology.

Test condition : Five groups of rabbits (2 males/dose at the 4 lower doses; 3 males and 1 female at the highest dose) were depilated over the entire trunk and an area of about 1 square inch was abraded. Doses of the test material in the form of 25 to 60 per cent aqueous pastes were applied to the skin and maintained for a 24-hour period under a plastic sleeve. After 24 hours, the excess material was washed off and the animals were observed for appearance, behavior, body weight, and mortality for 14 days. Skin irritation was scored according to Draize. The animals were sacrificed and examined grossly after the observation period.

Test substance : Antimony dialkyldithiocarbamate

Reliability : (2) valid with restrictions

Flag : Critical study for SIDS endpoint

13.07.2006 (2)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type : Sub-acute

Species : rat

Sex : male/female

Strain : Sprague-Dawley

Route of admin. : gavage

Exposure period : up to 54 days

Frequency of treatm. : daily

Post exposure period :

Doses : 0, 50, 250 and 1000 mg/kg bw/d

Control group : yes, concurrent vehicle

NOAEL : 1000 mg/kg bw

Method : other: OECD 422

Year : 2006

GLP : yes

Test substance : as prescribed by 1.1 - 1.4

Method : Clinical signs, behavioral assessments, body weight development, food and water consumption were monitored during the study. Hematology and blood chemistry were evaluated prior to mating on 5 animals per sex from each dose group. Pairing of animals within each dose group was undertaken on a one male: one female basis on day 15 of the study. During the lactation phase, clinical observations were performed on all surviving offspring, together with litter size and offspring weights and assessment of developmental landmarks. Extensive functional

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Result

observational observations were performed on 5 selected males and females from each dose group. Males were terminated on day 42, followed by termination of all surviving females and offspring on day 5 postpartum. All animals were subject to a gross necropsy examination and histopathological evaluation of selected tissues was performed.

: One male treated with 250 mg/kg bw/d was found dead on day 33, however this was not considered related to treatment. There were no clinical signs of toxicity, no effects observed in the functional observational battery, no effects on body weight change or food or water consumption, and no effects on hematology or blood chemistry. There were no treatment related macroscopic abnormalities for parental animals of either sex, no effects on organ weights and no histopathological findings.

Conclusion Reliability

: The NOEL for systemic toxicity was considered to be 1000 mg/kg bw/d.
: (1) valid without restriction
Guideline study

Flag

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: Critical study for SIDS endpoint

(8)

5.5 GENETIC TOXICITY 'IN VITRO'

Type

: Ames test

System of testing

: Salmonella strains TA98, TA100, TA1535, TA1537 and TA1538

Test concentration

: 100, 333, 1000, 3333, 5000 ug/plate

Cycotoxic concentr.

: > 5000 ug/plate

Metabolic activation

: with and without

Result

: negative

Method

: other: Ames et al (1975)

Year

: 1992

GLP

: yes

Test substance

: as prescribed by 1.1 - 1.4

Method

: Positive controls were plated concurrently with the assay (2-AA, 2-NF, Sodium azide, 9-AA). A negative control (vehicle) was also plated concurrently with the assay.

Result

: As required by the protocol for a valid test, the mean of the positive controls exhibited at least a three fold increase in the number of revertants over the mean value of the respective vehicle control.

The results of the dose range finding study indicate that a slight precipitate of the test substance forms, but no appreciable toxicity was observed. In the mutagenicity assay no positive responses were observed with any of the tester strains in the presence or absence of metabolic activation. Precipitate, but no appreciable toxicity was observed.

Test condition

: The assay was performed in two phases using the plate incorporation method, in the presence and absence of metabolic activation. The first phase, the dose range finding study, was used to establish the dose range for the mutagenicity assay. In the dose range finding study, the maximum dose tested was 5000 ug/plate. The test substance was dissolved in acetone. The second phase, the mutagenicity assay, was used to evaluate the mutagenicity of the test substance. In the mutagenicity assay, the dose levels were 100, 333, 1000, 3333, 1000 and 5000 ug/plate.

Test substance

: Antimony dipentylidithiocarbamate; lot EVR-384-281

Reliability

: (1) valid without restriction

Flag

: Critical study for SIDS endpoint

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5.6 GENETIC TOXICITY 'IN VIVO'

Type : Micronucleus assay
Species : mouse
Sex : male/female
Strain : ICR
Route of admin. : i.p.
Exposure period :
Doses : 1250, 2500 or 5000 mg/kg
Result :
Method : OECD Guide-line 474 "Genetic Toxicology: Micronucleus Test"
Year : 1992
GLP : yes
Test substance :

Result : In the absence of mortality in the pilot study, the maximum dose level used for the micronucleus study was 5000 mg/kg. No mortality or clinical signs were observed in the micronucleus assay. Bone marrow cells, collected at 24, 48, or 72 hours after treatment, did not show a reduction in the ratio of polychromatic erythrocytes to total erythrocytes suggesting the test substance did not induce bone marrow toxicity. No significant increase in micronucleated polychromatic erythrocytes was observed at 24, 48 or 72 hours after dose administration in the male mice. A significant increase in micronucleated polychromatic erythrocytes was observed at dose levels of 2500 and 5000 mg/kg in female mice, only at the 48 hour sampling time.

In the confirmatory assay, no mortality or clinical signs were observed in either male or female animals. No reduction in the ratio of polychromatic erythrocytes to total erythrocytes was observed in any treatment group, suggesting the test substance did not induce bone marrow toxicity. No significant increase in micronucleated polychromatic erythrocytes was observed in the male mice; a significant increase in micronucleated polychromatic erythrocytes was observed at dose levels of 2500 and 5000 mg/kg in female animals.

Test condition : Male and female ICR mice were exposed to 1250, 2500 or 5000 mg/kg of the test substance which was administered in a total volume of 20 ml/kg as a single ip injection. The vehicle used was corn oil. For the micronucleus assay, animals were assigned to 13 groups of 5 animals/sex. An additional group of 5 animals/sex was designated as replacement animals and were dosed with the high dose of test substance in case of mortality prior to scheduled sacrifice. 5 animals/sex/group were sacrificed after 24, 48 and 72 hours following dose administration. 5 animals/sex were administered a positive control (cyclophosphamide, 30 mg/kg) and sacrificed after 24 hours.

Polychromatic erythrocytes were scored for the presence of micronuclei. The number of micronucleated normocytes in the field of 1000 polychromatic erythrocytes was enumerated. The proportion of polychromatic erythrocytes to total erythrocytes counted was also recorded.

In the confirmatory micronucleus assay 6 animals per sex were assigned to four groups (vehicle control, 2500 and 5000 mg/kg, and positive control) and sacrificed after 48 hours.

Bone marrow cells were collected and examined for micronucleated polychromatic erythrocytes.

Test substance : Antimony dipentylthiocarbamate; lot EVR-384-281

Conclusion : The results of the initial and confirmatory assay indicate that under the conditions of this study, the test substance did induce a significant increase in micronucleated polychromatic erythrocytes in female ICR mice. Significant inter-animal variability was observed in the dose groups that were significantly elevated above the vehicle control group. The test substance was concluded to be weakly positive in the mouse micronucleus assay.

Reliability : (1) valid without restriction

Flag : Critical study for SIDS endpoint

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(4)

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

Type : One generation study

Species : rat

Sex : male/female

Strain : Sprague-Dawley

Route of admin. : gavage

Exposure period : up to 54 days

Frequency of treatm. : daily

Premating exposure period

Male : 15 days

Female : 15 days

Duration of test : up to 54 days

No. of generation studies : 1

Doses : 0, 50, 250 and 1000 mg/kg bw/d

Control group : yes, concurrent vehicle

NOAEL parental : 1000 mg/kg bw

NOAEL F1 offspring : 1000 mg/kg bw

Result : No effects at the highest dose tested (1000 mg/kg bw/d)

Method : OECD Guide-line 422

Year : 2006

GLP : yes

Test substance : as prescribed by 1.1 - 1.4

Method : Pairing of animals within each dose group was undertaken on a one male: one female basis on day 15 of the study. During the lactation phase, clinical observations were performed on all surviving offspring, together with litter size and offspring weights and assessment of developmental landmarks. Males were terminated on day 42, followed by termination of all surviving females and offspring on day 5 postpartum. All animals were subject to a gross necropsy examination and histopathological evaluation of selected tissues was performed.

Result : There were no effects on mating performance or fertility. There were no intergroup differences for litter size, sex ratio or viability. There were no effects on offspring development. There were no clinically observable signs of toxicity in offspring from treated animals.

Conclusion : No treatment related effects on reproduction were evident. The NOEL for reproductive toxicity was considered to be 1000 mg/kg bw/d.

Reliability : (1) valid without restriction

Guideline study

Flag : Critical study for SIDS endpoint
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5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : gavage
Exposure period : up to 54 days
Frequency of treatm. : daily
Duration of test : to day 5 postpartum
Doses : 0, 50, 250 and 1000 mg/kg bw/d
Control group : yes, concurrent vehicle
NOAEL maternal tox. : 1000 mg/kg bw
NOAEL teratogen. : 1000 - mg/kg bw
Result : no effects on development at the highest dose tested (1000 mg/kg bw/d)
Method : other: OECD 422
Year : 2006
GLP : yes
Test substance : as prescribed by 1.1 - 1.4

Method : Pairing of animals within each dose group was undertaken on a one male: one female basis on day 15 of the study.
During the lactation phase, clinical observations were performed on all surviving offspring, together with litter size and offspring weights and assessment of developmental landmarks. Offspring were sacrificed on day 5 postpartum. All animals were subject to a gross necropsy examination and histopathological evaluation of selected tissues was performed.

Result : There were no clinically observable signs of test material toxicity detected in offspring from treated animals. There were no treatment related abnormalities detected for interim death or terminal sacrifice offspring.

Conclusion : The NOEL for developmental effects in offspring from treated animals was 1000 mg/kg bw/d, the highest dose tested.

Reliability : (1) valid without restriction
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5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES**5.9 SPECIFIC INVESTIGATIONS****5.10 EXPOSURE EXPERIENCE****5.11 ADDITIONAL REMARKS**

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

9. References

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- (1) EPIWIN v. 3.11
- (2) Food and Drug Research Laboratories, Inc. (1961) The Acute Dermal Toxicity for Rats of Antimony Diamyl Dithiocarbamate (Compound OD 596). Laboratory No. 81447
- (3) Food and Drug Research Laboratories, Inc. (1961) The Acute Oral Toxicity for Rats of Compound OD 596. Laboratory No. 81447A
- (4) Putnam, DI and Morris, MJ (1992) Micronucleus Cytogenetic Assay in Mice, Antimony Dipentylidithiocarbamate. Microbiological Associates, Inc. Study Number TA214.122
- (5) RT Vanderbilt (2006) Personal communication with E bendig, Product Risk Manager.
- (6) SafePharm Laboratories (2006) Assessment of Ready Biodegradability; CO2 Evolution Test. SPL Project Number 0860/0107
- (7) SafePharm Laboratories (2006) Determination of Wtaer Solubility. SPL Project Number 0860/0125
- (8) SafePharm Laboratories (2006) Oral (gavage) Combined Repeat Dose Toxicity Study with Reproductive/Developmental Toxicity Screening Test in the Rat. Project No. 860/103
- (9) Safepharm Laboratories (2008) Vanlube 73 (R) Daphnia Reproduction Test. Project number 0860/0126.
- (10) San, RHC and Sly, JE (1992) Salmonella/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test), Antimony Dipentylidithiocarbamate. Microbiological Assocaites, Inc. Study Number TA214.501.

10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT